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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,379	08/15/2001	Christian Kropf	H03763/2006-219	8884

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PAUL & PAUL  
2000 MARKET STREET  
PHILADELPHIA, PA 19103-3229

EXAMINER
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KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

09/868,379

**Applicant(s)**

KROPF ET AL.

**Examiner**

Frederick Krass

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-21 is/are pending in the application.
- 4a) Of the above claim(s) 11,12,18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10,13-17,20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **Restriction Requirement**

Applicant's election of Group I in the reply filed on 03/20/07 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11, 12, 18 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### **Written Description Rejection (Insufficient Disclosure)**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The appearance of mere indistinct words (here the words "derivatives" and

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“natural substances”) in a specification or a claim, even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004).

The specification provides a very limited number of examples of “water soluble derivatives of water-insoluble polymeric natural substances” (at page 7, lines 8-12) “such as... cellulose ethers (methylcellulose, hydroxyethylcellulose, carboxymethylcellulose), hydroxyethylstarch or hydroxypropylguar”. That very narrow representative sampling (all modified polysaccharides) does not, however, allow one skilled in the art to visualize or recognize a reasonable number of other species within the full scope of that class (one potentially nearly infinite in scope).

### **Scope of Enablement Rejection**

Claims 8-10, 13-17, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for suspensions of nanometric particles surface-treated with a) C<sub>12</sub>-C<sub>16</sub>-fatty alcohol oligo-(1.4)-glycosides or ii) hydrogenated castor oil poly(60)-glycol ethers, respectively, does not reasonably provide enablement for suspensions of nanometric particles surface-treated with other types of adsorbants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art

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how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).<sup>1</sup>

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

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<sup>1</sup> As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is “undue”, not “experimentation”.

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to suspensions of surface treated, poorly soluble calcium salts, e.g., hydroxyapatite. The relative skill of those in the art is high, that of a postgraduate chemical engineer or pharmaceutical chemist. That factor is outweighed, however, by the unpredictable nature of the art.

As illustrative of the state of the art, the examiner cites Japanese Patent Document 6-329557. This prior art document clearly teaches that selection of surface treating agents suitable for the preparation of stable nanometric hydroxyapatite suspensions is a strictly empirical undertaking, with even minor changes leading to unexpected failure. See, e.g., paragraph 0020 (albumin produces stable dispersions, while gelatin causes aggregation) and paragraph 0026 (polyhydric organic acids work, monohydric acids do not).

2. The breadth of the claims

The claims recite various genera of adsorbants (surface treating agents) which are very broad in scope, e.g., "water-soluble derivatives of water-insoluble natural polymeric substances", "water-soluble surfactants", etc.

3. The amount of direction or guidance provided and the presence or absence of working examples

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The specification provides no direction or guidance for preparing dispersions using any surface treating agents other than a) C<sub>12</sub>-C<sub>16</sub>-fatty alcohol oligo-(1.4)-glycosides or ii) hydrogenated castor oil poly(60)-glycol ethers, respectively (the surfactants used in examples 1.1 through 1.6 at pages 12-15).

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that a reasonably representative number of adsorbants within the scope of the instant claims could be predictably used to produce hydroxyapatite suspensions as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

### **Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “water-soluble derivatives of water-insoluble natural polymers” is unclear in meaning. The term “derivative” is indefinite because it is not readily apparent how far one can deviate from the parent compound without the “derivative” being so far removed therefrom as to be a completely different compound. Similarly, it is not clear how a “natural” polymeric substance is to be differentiated from the same polymer made in the lab. And finally, since the only examples of such derivatives (cellulose ethers, methylcellulose, hydroxyethylcellulose, carboxymethylcellulose, hydroxyethylstarch and hydroxypropylguar) are also recited (see the related rejection in the “Written Description” section supra), it is not clear how the former are distinguishable from the latter.



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### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-10, 13-17, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudin et al (USP 6,919,070) in view of Oda et al (full English language translation of Japanese Patent Document 6-329557).

The primary reference discloses remineralizing toothpastes (column 1, lines 19-38) comprising 1 to 50, preferably 2 to 20 percent by weight (column 1, lines 58-63) nanometric hydroxyapatite particles having rod-like (anisotropic) dimensions, i.e., diameters of 1 to 100nm and lengths of 10 to 200nm; see the abstract. The toothpastes contain various conventional ingredients, including up to 25 percent by weight silica abrasives (column 3, lines 48-52) and up to 5 percent by weight nonionic surfactants (column 3, lines 38-41). The reference differs from the instant claims insofar as surface-treatment is not specified, although the reference clearly teaches at column 3, lines 11-15 that “the product will comprise a liquid phase containing humectants and binding thickeners which act to maintain the particulate solid abrasive and HA crystals in the form of stable suspension in the liquid phase” (emphasis added).

The secondary reference teaches that stability of hydroxyapatite suspensions can be improved by surface treating the particles with albumin or a polycarboxylic acid. The optimal proportion of surface treating agent was found to be 5 percent by weight, based on the weight of the hydroxyapatite particles (paragraph 0023). Although nanometric particles are disclosed (see paragraph 0009, for example), the prior art differs from the instant claims insofar as it does not specify “rod-like” (anisotropic) particles.

It would have been obvious to have surface-treated the hydroxyapatite particles of the primary reference suspensions with albumin or a polycarboxylic acid, motivated by the desire to improve suspension stability as taught by the secondary reference.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

